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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/462,094 | 01/11/2000 | PETER K.T. PANG | P8061-9012 | 4670 |

7590 12/24/2002

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EXAMINER

BORIN, MICHAEL L

| ART UNIT | PAPER NUMBER |
|----------|--------------|
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1631

DATE MAILED: 12/24/2002

12

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/462,094

Applicant(s)

Pang et al.

Examiner

Michael Borin

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Oct 15, 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 and 3-20 is/are pending in the application.
- 4a) Of the above, claim(s) 3-6, 9-14, and 16-18 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 7, 8, 15, 19, and 20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 6) ☐ Other:

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DETAILED ACTION

Status of Claims

1. Amendment filed 10/15/02 is acknowledged. Claim 2 is canceled. Claims 19,20, which replace the canceled claim 2, are added. Claims 1, 3-20 are pending. Claims 3-6,9-13,14,16-18 remain withdrawn from consideration, as being drawn to a non-elected groups.
2. Rejection of claim 2 under 35 U.S.C. 112, second paragraph, is withdrawn in view of cancellation of the claim.

Claim Rejections - 35 USC § 102 and 103.

3. Rejection of claims 1,7 under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C.103(a) as obvious over Dupont et al (US Patent 5,618,925) is maintained for the reasons of record.

Applicant's arguments about effect of lyophilization are noted but are not deemed convincing. First, the reference discloses variety of extracts obtained from shark cartilage, not necessarily subject to lyophilization. See, e.g., paragraph bridging columns 2 and 3 (col. 3, lines 14,15, in particular), and col. 3, lines 25-29. Second,

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the instant claims are not limited to any particular physical state of the extract, and read equally on solid and liquid extracts.

In regard to the anti-PTH activity of the extract, as was discussed in the previous Office action, it has been held that where applicant claims a composition in terms of function, property or characteristic where said function is not explicitly shown by the reference and where the examiner has explained why the function, property or characteristic is considered inherent in the prior art, it is appropriate for the examiner to make a rejection under both the applicable section of 35 USC 102 and 35 USC 103 such that the burden is placed upon the applicant to provide clear evidence that the respective compositions do in fact differ. No showing that extracts taught in Dupont do not have anti-PTH activity has been provided in applicant's response.

4. Claims 15, 19,20 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C.103(a) as obvious over Dupont et al (US Patent 5,618,925). The rejection is maintained for the reasons of record as applied to claims 2,15 in the previous Office action (paragraph #6).

Applicant argues that "in the present invention the supernatant is lyophilized". No lyophilization step was identified in the instant claims.

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5. Claim 8 remains rejected under 35 U.S.C.103(a) as obvious over Halperin et al (US Patent 5,512,591) and Dupont et al (US Patent 5,618,925). The rejection is maintained for the reason of record.

Applicant argues that Halperin does not disclose shark extract which retains activity after lyophilization. As discussed in the previous paragraph, the instant claims do not describe lyophilization step either.

Conclusion.

6. No claims are allowed

7. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing

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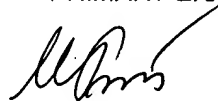
date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Borin whose telephone number is (703) 305-4506. Dr. Borin can normally be reached between the hours of 8:30 A.M. to 5:00 P.M. EST Monday to Friday. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. Michael Woodward, can be reached on (703) 308-4028. The fax telephone number for this group is (703) 305-3014.

Any inquiry of a general nature or relating the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

MICHAEL BORIN, PH.D
PRIMARY EXAMINER

December 20, 2002



mlb